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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,084	05/06/2005	Ajit Lalvani	GRT/3772-22	9379
23117 7590 10/02/2007 NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			EXAMINER GRASER, JENNIFER E	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 10/02/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/520,084

Applicant(s)

LALVANI ET AL.

Examiner

Jennifer E. Graser

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19, 23, 24, 26-28 and 95 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-19, 23, 24, 26-28 and 95 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-19, drawn to a method of diagnosing in an individual recent exposure to an agent which is a pathogen, vaccine or any other moiety which induces a cellular response, said method comprising determining whether the T cells of the individual recognize a protein from said agent having a length of at least 30 amino acids, to a greater extent than one or more peptide epitopes from the agent, a greater extent of recognition of the protein indicating that the individual has recently been exposed to the agent. **NOTE: If this Group is elected, Applicant must elect a single protein in the assay from SEQ ID Nos: 1-35. This is a Restriction Requirement, not a species election.**

Group II, claim(s), 23 and 95, drawn to a product comprising a protein which is at least 30 amino acids and one or more peptide epitopes. **NOTE: If this Group is elected, Applicant must elect a single protein and peptide epitopes which the product is comprised of, e.g., from SEQ ID Nos: 1-35. This is a Restriction Requirement, not a species election.**

Group III, claim(s) 24 and 26, drawn to a method of treating an individual comprising administering a product which prevents or treats a condition caused by a pathogen. **NOTE: If this Group is elected, Applicant must elect a single product which is to be used in the method, e.g., from SEQ ID Nos: 1-35. This is a Restriction Requirement, not a species election.**

Group IV, claim(s) 27 and 28, drawn to a kit comprising one or more peptide epitopes and a protein. **NOTE: If this Group is elected, Applicant must elect a single product which is to be used in the method, e.g., Applicants must recite the specific protein and**

or epitopes which are the main ingredients in the kit. This is a Restriction Requirement, not a species election.

2. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group I is not novel. See WO 00/26248 which teaches the invention of Group I. Accordingly, Group I lacks unity with the other Groups. The inventions of Groups II, III and IV also do not relate to a single general inventive concept as they contain different special technical features. The product of Group II is not required to be used in the method of Group I. The methods of Groups I and II require completely different method steps, have different objectives and different outcomes and, therefore, do not relate to a single inventive concept. The kit of Group IV does not require the products of Group II and, therefore, does not share a special technical feature. It is noted that no International Search Report was prepared for claims 22-25, 27-28, 50-51, 71-73 and 92-94 which correspond to the instantly pending claims. The EPO determined that the claims relate to such an extremely large number of possible products which may be obtained from any pathogen that a meaningful search over the whole of the claimed scope was not possible. The claims have not been amended since and still contain an unduly broad scope that even a proper Restriction was difficult to establish. Applicants are required, as outlined above, to elect a single product or combo of products to be used in the claimed methods or as the main ingredient in the kit since they are only entitled to the search of one product per application.

Art Unit: 1645


3. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 7:30 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

  
Jennifer Graser  
Primary Examiner  
Art Unit 1645  
9/26/07